### UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

David Behar, M.D.

Plaintiff,

v.

No. 2:23-cv-01924-PD

U.S. Food and Drug Administration, et

Defendants.

### DEFENDANTS' COMBINED OPPOSITION TO ENTRY OF DEFAULT AND CROSS-MOTION TO DISMISS AND MEMORANDUM IN SUPPORT

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Pursuant to Federal Rule of Civil Procedure 12(b)(5), Defendants U.S. Food and Drug Administration ("FDA"), Robert Califf, M.D., the U.S. Department of Health and Human Services, and Xavier Becerra (collectively, "Defendants") move to dismiss this action for insufficient service of process, in violation of Federal Rule of Civil Procedure 4(m). Plaintiff has not properly served Defendants within 90 days from filing his Complaint as required by Rule 4(m). Plaintiff attempted service via FedEx, rather than registered or certified mail as required to serve federal agencies or officers under Federal Rule of Civil Procedure 4(i). This is Plaintiff's third attempt to pursue substantially identical claims in this Court, and the third time he has failed to properly serve Defendants. He has not shown good cause for that failure, and there is no basis for this Court to exercise its discretion to extend his time to effect service. Plaintiff's motion for entry of default should be denied, and this case should be dismissed, for insufficient service of process.

#### **BACKGROUND**

Plaintiff Dr. David Behar, proceeding *pro se* on behalf of himself and his patients, alleges that the U.S Food and Drug Administration ("FDA") has violated various provisions of federal law by conditioning its approval of the antipsychotic drug clozapine on a Risk Evaluation and Mitigation Strategy ("REMS"). *See generally* ECF No. 1 ("Compl."). A REMS "is a drug safety program that [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." *See generally* FDA, *Risk Evaluation and Mitigation Strategies* (May 16,

2023), https://perma.cc/ELH9-382C. Plaintiff alleges that the Clozapine REMS requires, *inter alia*, that patients taking the drug be monitored through regular bloodwork according to a specific schedule. Compl. ¶ 2; *see also generally* Clozapine Prod. Mfrs. Grp., *Clozapine REMS* (last visited Sept. 1, 2023), https://perma.cc/YD22-UTWB. Plaintiff believes this blood monitoring requirement is "oppressive and unconstitutional." Compl. ¶ 3.

This is the third time in as many years that Plaintiff has filed substantially identical challenges to the Clozapine REMS in this Court.<sup>1</sup>

Behar I. Plaintiff filed his first clozapine suit in November 2020. See Compl., ECF No. 1, Behar v. FDA (Behar I), No. 2:20-cv-05597-PBT (E.D. Pa. Nov. 5, 2020). After Plaintiff did not serve any Defendant with process for more than four months, Defendants filed a motion to dismiss for failure to complete service within the 90 days allowed under Federal Rule of Civil Procedure 4(m). See Defs.' Mot., ECF No. 4, Behar I (E.D. Pa. Mar. 22, 2021). After Plaintiff did not respond for another three months, this Court dismissed his suit without prejudice. Order, ECF No. 5, Behar I (E.D. Pa. June 30, 2021).

Behar II. Plaintiff filed his second suit shortly after the first was dismissed. See Compl., ECF No. 1, Behar v. FDA (Behar II), No. 2:21-cv-03130-PBT (E.D. Pa. July 9, 2021). That suit was mistakenly dismissed for failure to pay the filing fee, which Plaintiff had

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<sup>&</sup>lt;sup>1</sup> Plaintiff's previous suits were assigned to the Hon. Petrese B. Tucker, who assumed inactive status in July 2022. For the sake of simplicity, Defendants refer to "this Court" regardless of whether a particular proceeding took place before Judge Tucker or before the Hon. Paul S. Diamond.

in fact timely paid. *See* Order Reinstating Complaint, ECF No. 6, *Behar II* (E.D. Pa. Feb. 17, 2022). This Court then ordered Plaintiff to "properly serve Defendants within 30 days" of his suit's reinstatement. *Id.* More than three months after that order (and close to a year after the case was initially filed), Plaintiff still had not effected valid service. While Plaintiff had served a summons and complaint on FDA, he had not served either the Attorney General of the United States or the U.S. Attorney for the Eastern District of Pennsylvania, as required by Rule 4(i). *See* Defs.' Mot., ECF No. 7 at 4, *Behar II* (E.D. Pa. June 7, 2022). Shortly after Defendants moved to dismiss on that basis, *see id.*, Plaintiff voluntarily dismissed the case without prejudice, *see* ECF No. 8, *Behar II* (E.D. Pa. June 23, 2022).

Behar III. Plaintiff commenced this suit on May 19, 2023. See ECF No. 1. About five weeks later, he filed a "Proof of Service" attesting that Defendants had been served "pursuant to Fed. R. Civ. P. 4(i)(1) and 4(i)(2) by Federal Express Standard Overnight service with delivery signatures required." ECF No. 6 at 3. On August 18—91 days after filing suit—Plaintiff moved for the Clerk to enter a default as to all Defendants. ECF No. 8. In an accompanying affidavit, Plaintiff stated that the named Defendants, as well as the Attorney General and the United States Attorney "as required under Fed. R. Civ. P. 4(i)(1), were properly served via Federal Express." ECF No. 8-1 at ¶ 4.

#### ARGUMENT

I. Entry of Default Is Inappropriate Because Defendants Have Not Been Properly Served.

Entry of default is not permitted "where proper service of the complaint is lacking." *Church-El v. Bank of N.Y.*, Civ. No. 11-877 (NLH/KMW), 2013 WL 1190013, at \*4 (D. Del. Mar. 21, 2013) (collecting cases); *see also Petrucelli v. Bohringer & Ratzinger*, 46 F.3d 1298, 1304 (3d Cir. 1995) ("[I]f a default judgment had been entered where there had not been proper service, the judgment is, *a fortiori*, void . . . ."). Default may not be entered against an improperly served defendant even if the legally defective service provided actual notice of the case. *Church-El*, 2013 WL 1190013 at \*6 n.7 (quoting *Grand Entm't Grp.*, *Ltd. v. Star Media Sales, Inc.*, 988 F.2d 476, 492 (3d Cir. 1993)).

Since Plaintiff is "the party asserting the validity of service," he "bears the burden of proof on that issue." *Grand Entm't*, 988 F.2d at 488. And all plaintiffs—whether *pro se* or not—are required to comply with the service rules. *See Ayres v. Jacobs & Crumplar*, *P.A.*, 99 F.3d 565, 569 (3d Cir. 1996). Plaintiff's submissions prove that Defendants have *not* been properly served, and the motion for entry of default must be denied.

Because Defendants are officers and agencies of the United States, Rule 4(i) provides the requirements for valid service. As relevant here, Rule 4 required that a person other than Plaintiff send copies of the summons and complaint "by registered or certified mail" (1) "to the Attorney General of the United States," (2) "to the civil-process clerk at the United States attorney's office" for the Eastern District of Pennsylvania, and

(3) to each one of the federal agencies and officers named as a defendant. Fed. R. Civ. P. 4(i)(1)(A)(ii), 4(i)(1)(B), 4(i)(2), 4(c)(2) (emphasis added).

On its face, service by FedEx does not satisfy those requirements because it is neither "registered [n]or certified mail." *E.g., Hin v. U.S. Dep't of Justice U.S. Marshalls Serv.*, No. 2:21-cv-00393-TLN-JDP, 2022 WL 705617, at \*7-8 (E.D. Cal. Mar. 9, 2022); *Shepard v. U.S. Dep't of Veteran Affairs*, No. 18-cv-01098-PAB-KMT, 2019 WL 5095680, at 2 (D. Colo. July 11, 2019). The plain meaning of those terms describes specific "class[es] of postal matter delivered by the United States Postal Service; . . . [not] delivery by a private carrier such as [FedEx]." *See Burgess v. Shima*, No. 21-cv-401-JDP, 2021 WL 5811225, at \*3-4 (W.D. Wis. Dec. 7, 2021) (interpreting analogous provision of Wisconsin law requiring state to be served by certified mail).

# II. Dismissal Is Warranted Because Plaintiff Has Repeatedly Failed to Complete Timely Service on the United States.

After filing this suit on May 19, 2023, Plaintiff had 90 days—until August 17, 2023—to properly serve Defendants. Fed. R. Civ. P. 4(m). Since he failed to do so, this Court "must dismiss the action without prejudice . . . or order that service be made within a specified time." The Court "must extend the time for service" only if Plaintiff "shows good cause for the failure." *Id*.

The Third Circuit has explained that when considering whether to dismiss or to extend time under Rule 4(m), courts should address two distinct questions: "First, the district court should determine whether good cause exists for an extension of time. If good cause is present, the district court must extend time for service and the inquiry is

ended. If, however, good cause does not exist, the court may in its discretion decide whether to dismiss the case without prejudice or extend time for service." *Petrucelli*, 46 F.3d at 1305.

# A. Plaintiff Cannot Show Good Cause for Failing to Serve Defendants Properly.

"In determining whether good cause exists, a court's primary focus is on the plaintiff's reasons for not complying with the time limit in the first place." *Boley v. Kaymark*, 123 F.3d 756, 758 (3d Cir 1997). The Third Circuit has "equated good cause with the concept of excusable neglect . . . , which requires . . . some reasonable basis for noncompliance." *MCI Telecomms. Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1097 (3d Cir. 1995) (quotations omitted).

Plaintiff cannot show good cause here. Neither confusion about the Federal Rules nor simple "disregard for . . . the technical niceties of service" on the United States can excuse failure to comply with Rule 4(m). *Ayres*, 99 F.3d at 568; *see also Duc Long v. MTD Prods. Inc.*, Civ. No. 16-cv-4272, 2016 WL 9774503, at \*3 (E.D. Pa. Dec. 29, 2016) ("Although Plaintiffs claim they believed service had been proper, a misunderstanding of the law does not provide good cause for its nonadherence."). Indeed, the Third Circuit has previously rejected arguments that good cause existed for "ignor[ing] the unequivocal instructions of Rule 4(i) and [instead] us[ing] unauthorized methods" to serve federal agencies. *Chiang v. U.S. Small Bus. Admin.*, 331 F. App'x 113, 115-16 (3d Cir. 2009).

## B. This Court Should Not Relieve Plaintiff of the Consequences of Repeated Failure to Effect Proper Service.

In deciding whether to grant a discretionary extension of time to serve, courts may consider "any [] factor that may be relevant," including whether a party is represented by counsel. *Chiang*, 331 F. App'x at 116.<sup>2</sup> Dismissal is appropriate in this case because Plaintiff—a highly educated physician—was repeatedly warned about proper service under Rule 4(i), and continually ignored those warnings. *See*, *e.g.*, *Edwards v. Hillman Grp. Co.*, 847 F. App'x 112, 115 (3d Cir. 2021) (affirming dismissal of *pro se* prisoner's complaint where plaintiff had been "instruct[ed] that [he] must comply with Rule 4(i)," but "did not do so"); *Scott v. Md. State Dep't of Lab.*, 673 F. App'x 299, 306-07 (4th Cir. 2016) (affirming dismissal of *pro se* complaint where repeated attempts at service "lacked diligence and reasonableness" in "refus[ing] to follow the district court's specific instructions" on the mechanics of proper service); *Constien v. United States*, 628 F.3d 1207, 1217 (10th Cir. 2010) (affirming dismissal where *pro se* plaintiff had been warned of "faulty" service "several times").

Plaintiff has sued Defendants on the same claims, in the same Court, three times in three years. His claims were dismissed first for not serving process at all. The second

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<sup>&</sup>lt;sup>2</sup> Other factors may include "actual notice of the legal action; prejudice to the defendant; the statute of limitations on the underlying causes of action;" and "the conduct of the defendant." *Chiang*, 331 F. App'x at 116. On balance, these factors have limited relevance to this case. Defendants do not assert that they lacked actual notice of this action or will be prejudiced in their ability to defend it if Plaintiff is ultimately permitted to complete service. But conversely, there is no suggestion that Defendants' conduct shows an attempt to evade service, and there does not appear to be any risk that dismissal would result in otherwise timely claims being barred by a statute of limitations.

time, he voluntarily dismissed them rather than defend his failure to serve process correctly as ordered by this Court. He also had the benefit of Defendants' two motions to dismiss that stated exactly what service the Federal Rules required. Put simply, Plaintiff has "received ample opportunity and guidance regarding how to serve the [Defendants] and [has] been warned that a failure to do so would result"—indeed, has already resulted once—"in dismissal of his case." See LaPorte v. City of Philadelphia, No. 21-1937, 2023 WL 3034328, at \*4 (3d Cir. April 21, 2023). This Court should not excuse his continuing failure to do so here.

#### **CONCLUSION**

For these reasons, the Court should deny Plaintiff's motion for entry of default, and dismiss his suit without prejudice for insufficient service of process.

September 1, 2023

Respectfully submitted,

/s/ Gabriel I. Schonfeld
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### **CERTIFICATE OF SERVICE**

I certify that the foregoing document has been filed electronically and is available for viewing and downloading from the ECF System. Service was accomplished via ECF on the following parties who have consented to electronic service:

David Behar, M.D. dbeharmd@gmail.com

/s/ Gabriel I. Schonfeld
Gabriel I. Schonfeld